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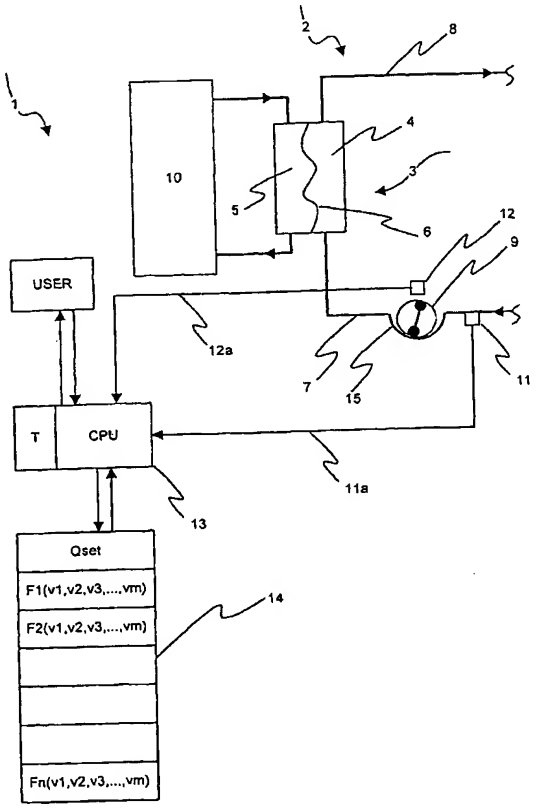

(57) Abstract: Equipment for controlling blood flow in an extracorporeal blood circuit, comprising at least a first sensor (11), designed to measure an arterial pressure (Part) upstream ofa peristaltic pump (9); at least a second sensor (12), designed to measure an angular velocity (Ω) of the peristaltic pump; a memory (14) designed to store at least one set value (Qset) of the desired blood flow through the access branch, and a calibration function (F) in at least the variables (vI), related to the angular velocity (Ω) of the pump, (v2), related to the arterial pressure (Part) in the portion of the said access branch upstream of the peristaltic pump, (v3), related to an actual flow of blood (Qactual) through the said access branch; and at least one control unit (13), capable of calculating an actual flow value (Qactual) by applying the function F to the values of angular velocity and arterial pressure (Part, Ω) measured by the sensors; comparing the actual flow (Qactual) with the desired flow (Qset); and varying the angular velocity of the said peristaltic pump if the Qactual - Qset lies outside a predetermined range.

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EQUIPMENT FOR CONTROLLING BLOOD FLOW IN AN EXTRACORPOREAL BLOOD CIRCUIT

DESCRIPTION

The present invention relates to equipment for controlling blood flow in an extracorporeal blood circuit.

In particular, the equipment to which the invention relates is designed to operate on extracorporeal circuits of blood treatment machines, for example machines for haemodialysis, haemofiltration, haemodiafiltration or plasmapheresis.

The machines for the treatments described above are typically used for processes of treating the blood of patients whose renal function is partially or totally compromised.

In particular, the blood treatment equipment indicated above typically comprises an extracorporeal circuit provided with at least one blood treatment unit, and with at least one access channel or branch designed to connect an area where blood is collected from the patient to a first chamber of the treatment unit; the extracorporeal circuit also comprises a second channel or return branch, extending downstream of the treatment unit from the said first chamber towards an area where the blood is returned to the patient.

In the access channel, there is also typically provided a peristaltic pump designed to act on the access channel to progressively move the blood flow towards the treatment unit.

It should be noted that, regardless of the type of dialysis treatment to be carried out on the patient, it is extremely important to know the precise quantity of blood collected from the patient and subsequently treated by the machine with which the extracorporeal blood circuit is associated.

In this respect, it should however be noted that the blood flow which can be obtained by using peristaltic pumps in the return portion of the extracorporeal circuit is actually dependent on various factors, the main ones of which are:

- the material, and consequently the elasticity, of the portion of line with which the peristaltic pump is associated;
- the geometry of the particular portion of the blood line with which the peristaltic pump is associated;
- the geometry of the pump rotor, and the angular velocity of the peristaltic pump;

- the pressure present, in particular, in the portions of tubing upstream and downstream of the peristaltic pump;
- the temperature of the extracorporeal circuit;
- the haematocrit value associated with the patient's blood;
- the geometry of the portion of tubing upstream of the pump;
- the geometry, and in particular the passage section, of the access member used to collect blood from the patient.

Formerly, when it was necessary to calculate the flow supplied by a peristaltic pump, this flow was considered to be proportional, according to a suitable conversion factor, to the instantaneous angular velocity of the pump.

In other words, the angular velocity of the pump segment was multiplied by a constant calibration factor in order to obtain a theoretical value of flow through the pump segment. According to circumstances, the resulting theoretical flow value was or was not shown on a suitable display of the machine.

However, because of the numerous factors mentioned briefly above, which affect the level of the flow actually supplied by the peristaltic pump, the calculation of the flow by means of a simple factor of proportionality with the angular velocity is clearly affected by errors which cannot be disregarded.

As will be easily understood, if, due to one or more of the described factors, the arterial pressure of the flow upstream of the pump reaches levels such that it impedes the movement of the blood flow provided by the peristaltic pump, the pump will produce an actual flow which is smaller than the estimated theoretical value. Moreover, an increase in the angular velocity set for the pump is accompanied by an increase in the pressure drop created upstream of the pump, which will evidently amplify the effects briefly described above.

Additionally, it must be emphasized that the pressure conditions upstream of the pump not only depend on the velocity and characteristics of the pump, but are also closely related to the form of access device (needle or other) used for connection to the patient's vascular system. In particular, in the case of needles, the procedures by which these needles are inserted into the patient's fistula, the conditions of the fistula, and the physiological condition and haematocrit value of the patient are all significant factors.

The actual flow produced by the pump can even vary during a single treatment as a result of variations in the arterial pressure upstream of the pump, which, evidently, significantly modify the mode of operation of the pump.

As mentioned above, the structure, in terms of materials and geometry, of the portion of tubing on which the pump acts can have a major effect on the flow which is

actually generated by the peristaltic pump, where other conditions are held constant. In this connection, it should be noted that the dynamic behaviour of the tubing portion and pump is variable, with respect to the time elapsing from the start of the treatment cycle, as a result of a deterioration, or more generally a variation, of the mechanical properties of the materials forming the line.

With the aim of overcoming the drawbacks described above, and of providing equipment for blood treatment in which it would be possible to know a flow value as close as possible to the flow actually passing through the pump portion of the extracorporeal circuit, U.S. Patent No. 5,733,257 describes a method of calibrating a peristaltic pump, to be used with equipment provided with at least one internal flowmeter.

According to the invention described in the aforementioned patent, the method comprises the introduction of a fluid into the segment of tubing on which the pump acts, and the operation of the peristaltic pump at a constant rotation speed.

When the standard operating conditions have been reached, the pressure upstream of the portion of tubing on which the pump acts is measured, and the flow of fluid which actually passes through the pump portion is measured by means of the machine's internal flowmeter, in such a way that a pair of calibration values (actual flow and arterial pressure) are obtained as a function of the angular velocity of the pump which has been selected.

The process described above is repeated while the arterial pressure upstream of the pump is varied by suitable means in such a way as to obtain different pairs of values of arterial pressure and actual flow for a single value of angular velocity. At this point, a calibration curve is calculated, and used to determine a relationship between pressure and actual flow with respect to the angular velocity in question. By repeating the calibration criterion described above for different values of angular velocity, it is possible to create a set of calibration curves; when the machine is put into operation, the calibration curves are used to calculate the actual flow of the peristaltic pump, once the angular velocity of the pump and the pressure in the portion of tubing upstream of the pump have been determined by measurement. Also according to U.S. Patent No. 5,733,257, it is possible to use the information on the actual flow obtained by means of the aforesaid calibration curves to control the angular velocity of the pump, in order to match the actual flow with that which is desired for the purposes of the particular treatment to be carried out on the patient.

Given these aspects of the prior art, one object of the present invention is to provide novel equipment controlling blood flow in an extracorporeal blood circuit, which is easily applied and which, in particular, makes it possible to control and know

the actual flow passing through the peristaltic pump portion of the extracorporeal circuit, without any need to carry out preliminary calibration procedures on the machine, provided that the geometrical characteristics and the mechanical properties of the extracorporeal circuit are known.

In particular, a fundamental object of the invention is to provide novel equipment which enables the actual flow through the peristaltic pump portion to be determined and the peristaltic pump to be controlled by a feedback system, in order to make the actual flow which is generated essentially match the value which is set by the user or required by the treatment in progress.

A further and preferred object of the invention is to provide novel equipment which can also measure the actual flow with a close approximation, making allowance for the structural alteration undergone in time by the material of the portion of tubing on which the peristaltic pump acts.

These and further objects which will be made clearer by the following description are essentially achieved by equipment for controlling blood flow in an extracorporeal blood circuit according to what is described in the attached Claim 1.

Further characteristics and advantages will be made clearer by the following description of some preferred, but not exclusive, embodiments of equipment for controlling blood flow in an extracorporeal blood circuit according to the invention.

This description is provided below with the aid of the attached drawings, provided solely for guidance and therefore without restrictive intent, in which:

- Figure 1 is a schematic representation of equipment for controlling blood flow in an extracorporeal blood circuit according to the present invention;
- Figure 2 is a flow diagram which illustrates schematically the steps of the procedure which can be executed, during the operation of the equipment, by a control unit associated with equipment for controlling blood flow in an extracorporeal blood circuit according to the present invention.

With reference to the attached Fig. 1, this represents the whole of a piece of equipment for controlling blood flow in an extracorporeal blood circuit, which in turn is indicated by the number 2. The extracorporeal circuit 2 can be used, for example, for carrying out the extracorporeal circulation of blood, when the patient is to be subjected to treatments such as haemodialysis, haemofiltration, ultrafiltration, haemodiafiltration, or any other combination of the treatments listed here.

The extracorporeal circuit 2 conventionally comprises at least one blood treatment unit 3, formed by a first chamber 4 and at least one second chamber 5, separated from each other by a semi-permeable membrane 6. At least one access branch 7 extends between an area where blood is collected from a patient and the first

chamber of the said treatment unit 4; at least one peristaltic pump 9 is associated for operation with a pump tube section 15 of the said access branch of the extracorporeal circuit, and at least one return branch 8 extends downstream of the treatment unit, between the aforesaid first chamber 4 and an area where the blood is returned to the patient. Typically, means (not illustrated) of access to the patient's cardiovascular system are provided in the areas where the blood is collected from the patient and returned to him, these means consisting, for example, of needles of appropriate dimensions, catheters, or access devices of other kinds. It should be noted that the second chamber of the unit 3 can be connected, for example, to a device 10 (not shown in detail) for sending a dialysis liquid towards the second chamber and for removing from the second chamber a dialysate in which the waste products and excess water from the blood have been accumulated.

The equipment for controlling the blood flow 1 has at least a first sensor 11, located in the access branch, in a portion of the said branch upstream of the peristaltic pump 9, in such a way that an arterial pressure (Part) can be measured and a corresponding output signal 11a proportional to the said arterial pressure can be generated. In practice, the first pressure sensor 11 operates immediately upstream of the peristaltic pump and can measure the pressure in the portion of tubing interposed between the area where the blood is collected from the patient and the said peristaltic pump. It should be noted that a negative pressure, typically with respect to atmospheric pressure, is typically found in this portion.

The equipment 1 also comprises a second sensor 12, associated for operation with the peristaltic pump and designed to measure an angular velocity ω (omega) of the said pump and to generate a corresponding second output signal 12a, proportional to the rotation speed of the peristaltic pump. It should be noted that the sensors described above are connected for operation to a control unit 13 to which the sensors send the first and the second signals respectively.

The control unit 13, consisting for example of a CPU, is associated with a memory 14, designed to store at least one set value (Qset) of the desired blood flow through the access branch, and a calibration function in the variables v1, v2, v3, which are described more fully below. In greater detail, v1 is a variable related to the angular velocity of the pump, v2 is a variable related to the arterial pressure (Part) present in the portion of the said access branch upstream of the said peristaltic pump, and v3 is a variable related to an actual blood flow (Qactual) through the said access branch.

The control unit 13 according to the invention can execute a control procedure comprising the following operations:

- calculation of an actual flow value (Qactual) by application of the memory-resident calibration function F to the values of angular velocity (ω) and arterial pressure (Part) measured by means of the first and second sensors, described briefly above;
- comparison of the actual flow value (Qactual), calculated by means of the calibration function F, with the user-specified or memory-resident set flow value (Qset); it should be noted that the value Qset can be fixed or variable in time according to a profile determined by the treatment, depending on the requirements of the patient and the settings entered into the equipment;
- variation of the angular velocity of the peristaltic pump when the difference between the actual flow and the desired flow (Qactual – Qset) is outside a predetermined acceptability range.

In practice, the control unit, by measuring the values of arterial pressure and angular velocity of the pump by means of the sensors, can use the calibration function to calculate the actual flow value and to correct the velocity of the pump when the actual flow differs excessively from the desired flow value through the access branch of the extracorporeal circuit.

The control unit, which is provided with a timer device, can execute the operations described above at predetermined time intervals.

Figure 2 is a flow diagram showing a possible operating mode of the control unit 13, according to the present invention. In terms of operation, the control unit can operate both in a first operating mode, in which it waits for signals for activating and disabling the previously described control procedure entered by means of a manual command of the user, through a user interface device 15, and by means of manual entry of the set flow (Qset). In other words, in the first manual operating mode, the control procedure is activated and disabled by a manual command of the operator in charge, who also manually enters the value of Qset.

Alternatively, the control unit can operate in a second operating mode, in which the previously described control procedure is activated at the start of the treatment, in a fully automatic way. Where the implementation is concerned, the control unit can be dedicated to the equipment for controlling blood flow described herein, or can alternatively be integrated into the central control system of the machinery with which the equipment in question is associated.

Moving on to a more detailed analysis of the operating steps executed by the control unit of the equipment in question (see Fig. 2 for reference), we can see that the control unit must initially receive an activation signal, in the form of a manual command or a suitable automatic activation signal (Start in Fig. 2) received following

the execution of a particular treatment by the machinery with which the control equipment is associated. It should be noted that the control unit can activate the control procedure not only after an activation signal has been received, but also if, for any reason, the value of Qset or of the arterial pressure Part varies or is varied (block 100 in Fig. 2).

When the control procedure has been activated, the control unit reads the set value of Qset and the actual value of Part; the control unit then executes a step of verifying the stability of the arterial pressure Part (block 101), by commanding the measurement of the said arterial pressure at a predetermined instant T1 and at a successive instant T2, and by making a comparison between the difference between the arterial pressures at the instants T1 and T2 and a predetermined range of acceptability; if the arterial pressure is not stable, or in other words if ΔP = Part (T1) – Part (T2) falls outside a range of acceptability, the control unit waits for a predetermined time interval (block 102) and then repeats the steps of measuring the arterial pressure at two successive time intervals to verify its stabilization. When the stability of the arterial pressure has been verified, the control unit 13 commands the continuation of the procedure which comprises the calculation of the value of the actual flow Qactual (block 103), the subsequent comparison of the actual flow Qactual with the set flow value Qset (block 104) and the subsequent variation of the angular velocity of the peristaltic pump, if Qactual – Qset does not lie within a range of acceptability (blocks 105).

As shown in Fig. 2, a step of comparing the value of Part with a threshold value considered critical for the treated patient is specified before the variation of the angular velocity of the peristaltic pump. If the pressure is below this threshold value, the algorithm is exited and the operator is alerted, by a warning message relating to the occurrence of a limit pressure condition. Similarly, and particularly if the angular velocity of the pump has to be increased, a step of comparing the angular velocity of the peristaltic pump before the variation with an acceptable maximum velocity of the said peristaltic pump is executed. If the peristaltic pump has already reached a maximum value of angular velocity which it is undesirable to exceed, the control unit stops the procedure and sends a warning signal to the user interface, to inform the user that a limit velocity condition has been reached by the peristaltic pump, this condition evidently preventing the system from controlling the pump appropriately in order to provide an actual flow Qactual essentially equal to the desired value (Qset) which has been set.

It should be noted that the calibration function F can also have at least one further variable v4 related to a time (Ti) elapsed from the start of the administered

treatment. In practice, as soon as the treatment starts, the control unit stores a time data element relating to the instant of starting; the control unit can determine the time elapsed between the said instant of starting and each instant at which the said control procedure is executed, and can then calculate an actual flow value (Qactual) by applying the memory-resident calibration function F to the value of the said elapsed time (Ti) and to the values of angular velocity and arterial pressure (Part, ω) measured by means of the said sensors.

In a first embodiment of the invention, the calibration function F is of the type $v3 = [\ \sum_{i=0...n}\ a_i \bullet (v2)^{n-i} \bullet (v1)^i\ ] + C$, where a_i and C are experimentally determined known parameters. More simply, the calibration function F can be of the type

$v3 = a \bullet v1 + b \bullet v1 \bullet v2 + c \bullet v2 + d$,

where a, b, c, d are the experimentally determined known parameters, and where v1 is the angular velocity of the pump, v2 is the arterial pressure Part in the portion of the said access branch upstream of the said peristaltic pump, and v3 is an actual blood flow (Qactual) through the said access branch.

In particular, it was found that the following values of a, b, c, d (divided into two sets, each valid for a predetermined pressure range Part) can be used to obtain a suitable calibration function; in practice, the function F comprises two functions, F' and F", linked together with continuity, the first F' being valid in a first range of values of arterial pressure, and the second F" being valid in a second range of values of arterial pressure which follows the said first range.

Alternatively, when F is also a function of v4, the calibration function F is of the type $v3 = [\ \sum_{i=0...n}\ \sum_{k=0...m}\ a_i \bullet b_k \bullet (v2)^{n-i-k} \bullet (v1)^i \bullet (v4)^k\ ] + C$,

where a_i, b_k and C are experimentally determined known parameters. In this second case, the function F can be, more specifically, of the type

$v3 = (a \bullet v1 + b \bullet v1 \bullet v2 + c \bullet v2 + d) \bullet f(v4)$,

where a, b, c, d are experimentally determined known parameters and f(v4) is a function which is also known and experimentally determined in the variable v4.

It should also be emphasized that the memory 14 can be designed to store a plurality of calibration functions F1, F2, ... Fn, each at least in the variables v1, v2, v3 and if appropriate in the variable v4. Each of these calibration functions can in practice be applicable to a corresponding type of extracorporeal circuit. More precisely, if multiple types of extracorporeal circuit are in production, with pump tube portions differing from each other, for example in respect of materials and/or geometry or other characteristics, a corresponding appropriate calibration function can be provided for and associated with each of these types, and can be stored in the memory 14. Each function F can also be associated with a corresponding identification code of the

corresponding extracorporeal circuit, so that the user can simply select the type of circuit installed and thus automatically select the corresponding function F to be used for the calculation of Qactual. Finally, it should be specified that the function F can also be a function of one or more of the following additional variables: v5, related to the geometric characteristics of an access member connectable for operation to the said extracorporeal circuit; v6, related to the length of the portion of tube of the access branch upstream of the said peristaltic pump; v7, related to the pressure in the portion of access branch downstream of the peristaltic pump; v8, related to the temperature of the extracorporeal circuit; and v9, related to the haematocrit value of the blood of the treated patient.

In practice, when a plurality of previously stored functions F is available, each relating to a corresponding type of extracorporeal circuit, and each capable of allowing for the rotation speed of the pump, the pressure Part, the time elapsed from the start of the use of the circuit, the type of access member in use and the length of the line upstream of the pump, it is possible to provide a reliable determination of Qactual and a simple and flexible instrument for controlling the peristaltic pump.

The invention also relates to a software program comprising instructions for making a control unit, whether of the dedicated type or associated with the machinery of which the extracorporeal circuit is a subordinate component, capable of executing the steps of the control procedure described above. From the practical point of view, this program can be stored on a magnetic and/or optical recording medium, in a read only memory, or in a volatile computer memory, or can be carried by an electric or electromagnetic carrier. Finally, the invention also comprises a machine for blood treatment, which is capable of carrying out one or more of the following treatments:

- haemodialysis,
- haemofiltration,
- haemodiafiltration,
- pure ultrafiltration,
- plasmapheresis,

and which is also provided with equipment for controlling blood flow in an extracorporeal circuit as described and illustrated in the attached drawings.

CLAIMS

1. Equipment for controlling blood flow in an extracorporeal blood circuit, the said extracorporeal circuit having at least one blood treatment unit, at least one access branch extending between an area where blood is collected from a patient and the treatment unit, at least one peristaltic pump associated for operation with the said access branch of the extracorporeal circuit, and at least one return branch extending between the treatment unit and an area where the blood is returned to the patient, the said equipment comprising:

- at least a first sensor, designed to measure an arterial pressure (Part) in a portion of the said access branch upstream of the peristaltic pump, and to generate a corresponding first output signal proportional to the said arterial pressure (Part);
- at least a second sensor, designed to measure an angular velocity (ω) of the peristaltic pump and to generate a corresponding second output signal, proportional to the angular velocity of the said peristaltic pump;
- a memory designed to store at least one set value (Qset) of the desired blood flow through the said access branch, and a calibration function F in at least the following variables:
  - v1, related to the angular velocity of the pump (ω),
  - v2, related to the arterial pressure (Part) in the portion of the said access branch upstream of the peristaltic pump,
  - v3, related to an actual flow of blood (Qactual) through the said access branch;
- at least one control unit, connected for operation to the said sensors and to the said memory, for receiving the said first and second output signals and for storing the corresponding measured values of arterial pressure (Part) and angular velocity (ω) in the said memory, the said control unit being capable of executing a control procedure comprising the following operations:
  - calculating an actual flow value (Qactual) by applying the said memory-resident calibration function F to the values of angular velocity and arterial pressure (Part, ω) measured by means of the said sensors;
  - comparing the said actual flow value (Qactual) with the said set flow value (Qset);
  - varying the angular velocity of the said peristaltic pump if the difference between the actual flow and the desired flow (Qactual – Qset) lies outside a predetermined range.

2. Equipment according to Claim 1, characterized in that it also comprises a timer device connected for operation to the control unit, the said control unit being capable of executing the said control procedure at predetermined time intervals.

3. Equipment according to Claim 1, characterized in that it also comprises a user interface device capable of sending to the control unit at least one signal for activating the said control procedure and at least one signal for disabling it.

4. Equipment according to Claim 3, characterized in that the said user interface device is capable of receiving a manual setting of the set flow (Qset) and of transmitting this setting to the said control unit.

5. Equipment according to Claim 4, characterized in that the said control unit is capable of operating, selectively, either in a first operating mode, in which it waits for the said activating and disabling signals and the said manual setting of the set flow for activating the said control procedure, or in a second operating mode, in which it automatically executes the said control procedure during the said treatment.

6. Equipment according to Claim 1, characterized in that the said control procedure also comprises a step of verifying the stability of the said arterial pressure (Part).

7. Equipment according to Claim 6, characterized in that the step of verifying the stability of the said arterial pressure (Part) comprises the following sub-steps: measuring a first arterial pressure (Part1) at a predetermined instant (T1), measuring a second arterial pressure (Part2) at an instant (T2) following the said predetermined instant (T1), comparing a difference between the first and second arterial pressures with a predetermined range of acceptability, waiting for a predetermined time interval and repeating the said steps of measuring and the said step of comparing if the difference between the first and second arterial pressures does not lie within the said predetermined range of acceptability, and continuing the said control procedure if the difference between the first and second arterial pressures lies within the said predetermined range of acceptability.

8. Equipment according to Claim 6, characterized in that the said step of verifying the stability of the arterial pressure is executed before the said step of calculating the actual flow.

9. Equipment according to Claim 1, characterized in that the said steps of calculating an actual flow value (Qactual), comparing the said actual flow value (Qactual) with the said set flow value (Qset), and varying the angular velocity of the said peristaltic pump succeed each other in time.

10. Equipment according to Claim 9, characterized in that there is provided, after the said step of comparing the said actual flow value (Qactual) with the said set flow value (Qset), and before the said step of varying the angular velocity of the said peristaltic pump, a step of comparing the Part with a threshold value considered critical for the patient being treated, and in that, if the pressure is below this threshold value, an exit is made from the algorithm and the operator is alerted by means of a warning message relating to the occurrence of a limit pressure condition.

11. Equipment according to Claim 9, characterized in that there is provided, after the said step of comparing the said actual flow value (Qactual) with the said set flow value (Qset), and before the said step of varying the angular velocity of the said peristaltic pump, a step of comparing the angular velocity with an acceptable maximum value which can be imparted to the pump.

12. Equipment according to Claim 1, characterized in that the calibration function F also has at least the following further variable:

- V4, related to a time (Ti) elapsed from a start condition of the said control procedure,

the said control unit being capable of determining a time which has elapsed between the said start condition and each instant in which the said control procedure is executed, and of calculating an actual flow value (Qactual) by applying the said memory-resident calibration function F to the value of the said time (Ti) elapsed and to the values of angular velocity and arterial pressure (Part, ω) measured by means of the said sensors.

13. Equipment according to Claim 1, characterized in that the calibration function F is of the type $v3 = [\sum_{i=0...n} a_i \bullet (v2)^{n-i} \bullet (v1)^i] + C$,

where a_i and C are experimentally determined known parameters.

14. Equipment according to Claim 12, characterized in that the calibration function F is of the type $v3 = [\sum_{i=0...n} \sum_{k=0...m} a_i \bullet b_k \bullet (v2)^{n-i-k} \bullet (v1)^i \bullet (v4)^k] + C$,

where a_i, b_k and C are experimentally determined known parameters.

15. Equipment according to Claim 13, characterized in that the calibration function F is of the type $v3 = a \bullet v1 + b \bullet v1 \bullet v2 + c \bullet v2 + d$,

where a, b, c, d are experimentally determined known parameters.

16. Equipment according to Claim 14, characterized in that the said calibration function F is of the type $v3 = (a \bullet v1 + b \bullet v1 \bullet v2 + c \bullet v2 + d) \bullet f(v4)$,

where a, b, c, d are experimentally determined known parameters and f(v4) is a function which is also known and experimentally determined in the variable v4.

17. Equipment according to any one of the preceding claims, characterized in that the said memory is designed to store a plurality of calibration functions F1, F2, ... Fn, each at least in the variables v1, v2, v3, and each applicable to a corresponding one of a plurality of types of extracorporeal circuits.

18. Equipment according to Claim 17, characterized in that each of the said calibration functions F is also a function of the said variable v4.

19. Equipment according to Claim 18, characterized in that each of the said calibration functions F is also a function of at least one or more of the following further variables:

- v5, related to the geometrical characteristics of an access member connectable for operation to the said extracorporeal circuit;
- v6, related to the length of the portion of tube of the access branch upstream of the said peristaltic pump.

20. Equipment according to Claim 19, characterized in that the said function F comprises two functions F' and F", linked together with continuity, the first F' being valid in a first range of values of arterial pressure, and the second F" being valid in a second range of values of arterial pressure which follows the said first range.

21. Software program comprising instructions for making the control unit capable of executing the steps of the control procedure as claimed in one or more of the preceding claims.

22. Program according to Claim 21, characterized in that it is stored on a magnetic and/or optical recording medium.

23. Program according to Claim 21, characterized in that it is stored in a computer memory.

24. Program according to Claim 21, characterized in that it is carried by an electric or electromagnetic carrier.

25. Program according to Claim 21, characterized in that it is stored in a read only memory.

26. Machine for treating blood in an extracorporeal circuit, characterized in that it comprises equipment for controlling the blood flow according to any one of Claims 1 to 20.

27. Machine for treating blood in an extracorporeal circuit according to Claim 26, characterized in that it is capable of carrying out one or more of the following treatments:

- haemodialysis,
- haemofiltration,

- haemodiafiltration,
- pure ultrafiltration,
- plasmapheresis.

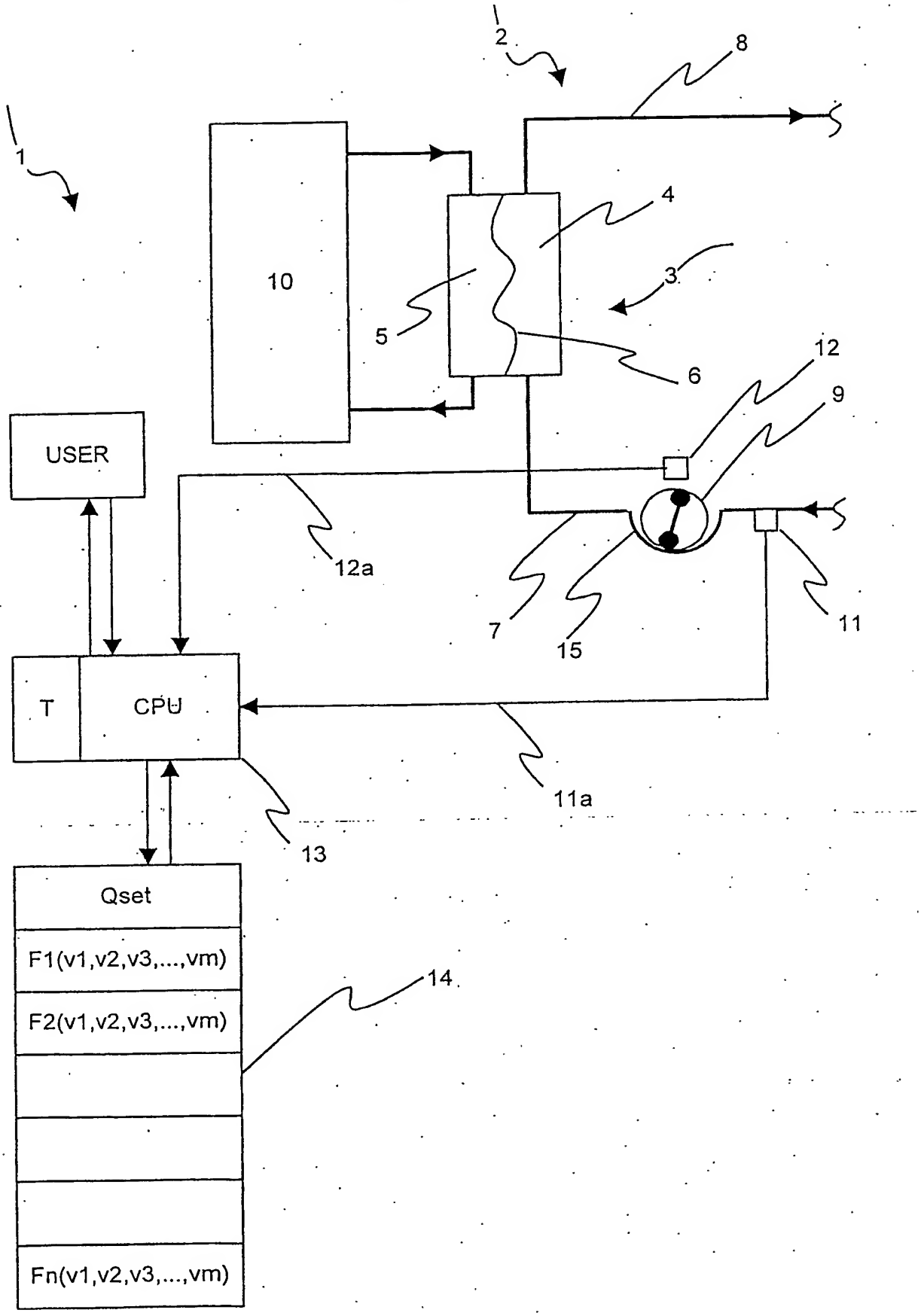
2
8
1
10
4
3
5
6
12
9
USER
12a
7
15
11
T
CPU
11a
13
Qset
F1(v1,v2,v3,...,vm)
F2(v1,v2,v3,...,vm)
14
Fn(v1,v2,v3,...,vm)

Fig. 1

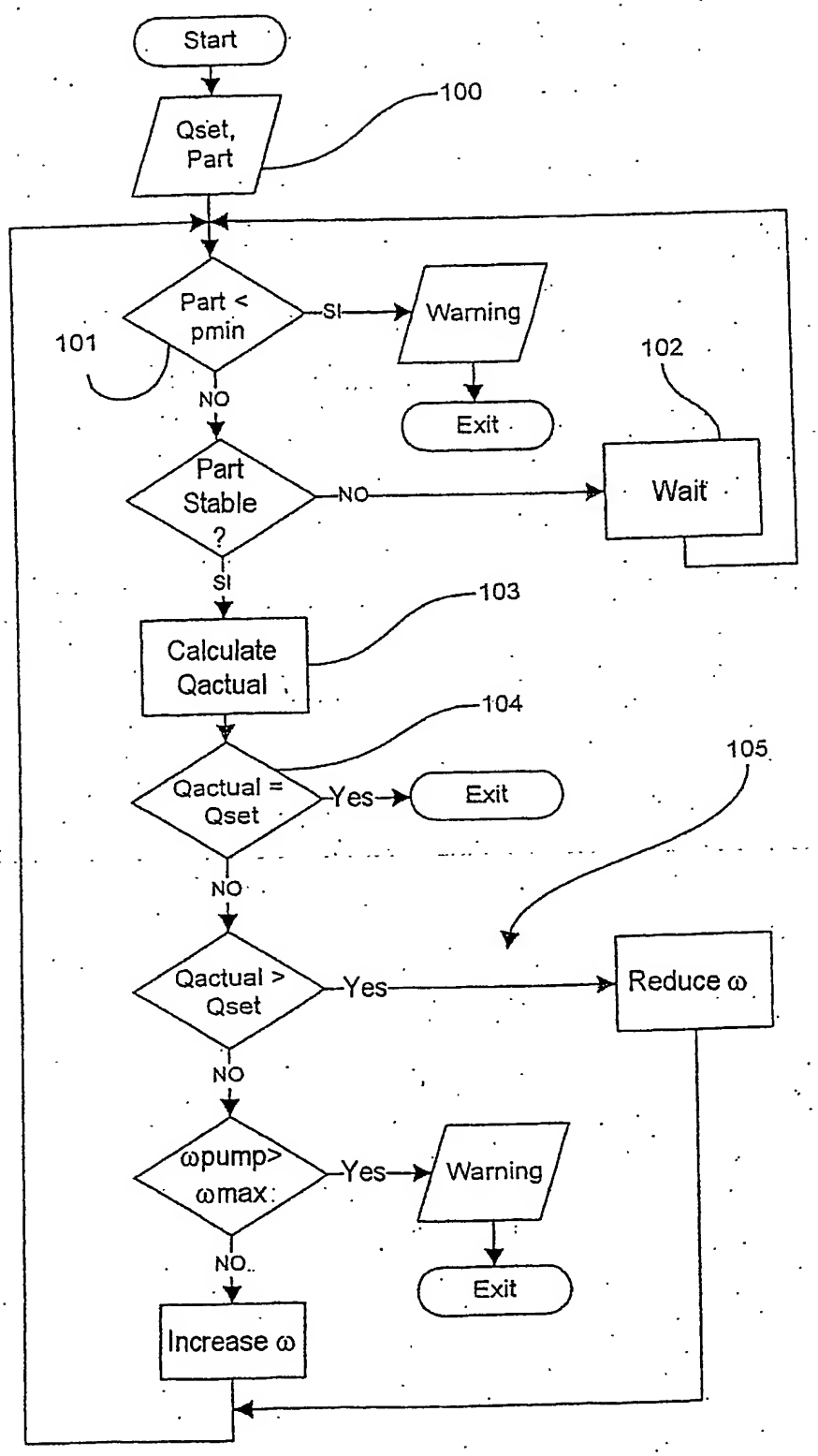
Start
Qset, Part
100
Part < pmin
SI
Warning
101
NO
Exit
102
Part Stable ?
NO
Wait
SI
103
Calculate Qactual
104
Qactual = Qset
Yes
Exit
105
NO
Qactual > Qset
Yes
Reduce ω
NO
ωpump> ωmax
Yes
Warning
NO
Exit
Increase ω

Fig. 2

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 02/05595

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M1/10 F04B43/12 F04B49/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M F04B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 733 257 A (STERNBY JAN) 31 March 1998 (1998-03-31) cited in the application column 7	1-20,26, 27
X	US 5 947 692 A (SAHLIN MARK P ET AL) 7 September 1999 (1999-09-07) claims	1-20,26, 27

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 March 2003	03/04/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Villeneuve, J-M

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB 02/05595

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 21-25
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(vi) PCT - Program for computers

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte[redacted]ional Application No
PCT/IB 02/05595

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5733257 A	31-03-1998	AT 200031 T	15-04-2001
		DE 69426985 D1	03-05-2001
		DE 69426985 T2	19-07-2001
		DK 723463 T3	30-04-2001
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		PT 723463 T	28-09-2001
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		WO 9923386 A1	14-05-1999